

REMARKS

Claims 1-29 are pending. Claims 5, 6, 9-21 and 26-29 are withdrawn from consideration as being directed to non-elected subject matter. Claims 1-4, 7-8, and 22-25 are amended herein, as discussed in detail below. Reconsideration of the claimed subject matter is respectfully requested in view of the above amendments to the claims and the following remarks.

Rejection of Claims 1 and 22 under 35 USC § 112, ¶ 2

The Examiner rejected Claims 1 and 22 under 35 U.S.C. 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner contended that it is unclear as to what the phrase "in isolation or in a mixture" at the end of these claims was intended to modify.

Although Applicants disagree with the Examiner's basis for rejecting Claims 1 and 22 as being indefinite in that it would be clear to one skilled in the art that the phrase allows the claims to encompass isolated *salts*, *solvates* or *prodrugs* of the claimed compounds as well as mixtures of *salts*, *solvates* or *prodrugs*, Applicants have amended, without prejudice, Claims 1 and 22 to remove this phrase in the interest of furthering the allowance of this application.

Rejection of Claims 1-4, 7, 22 and 23 under 35 USC § 102(b)

The Examiner rejected Claims 1-4, 7, 22 and 23 under 35 U.S.C. 102(b) as being anticipated by the teachings of DE 1,084,718 ("Lettre *et al.*"). In particular, the Examiner contends that:

*Lettre et al. teaches secosteroids such as 6-amino-5,6-secocholestane-3 $\beta$ ,5-diol and 6-dimethylamino-5,6-secocholestane-3 $\beta$ ,5 $\beta$ -diol (see cols. 3-4, Examples 1-4; see also attached English abstract, RNs 103099-54-3 and 105520-54-5). The reference teaches that the compounds are useful pharmaceuticals (see attached English abstract). The compounds and compositions taught by the reference are encompassed by the instant claims.*

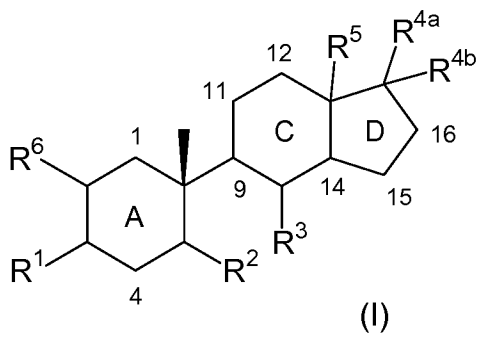
The Examiner also rejected Claims 1-4, 22 and 23 under 35 U.S.C. 102(b) as being anticipated by the teachings of JP 1,290,624 ("Oshida"). In particular, the Examiner contends that:

*Oshida teaches the 5,6-secoosteroids such as 5,6-secocholestane-1,3,6-triol as anticholesteremics and hypolipemics (see the English Abstract, RN 126922-88-*

1). The compounds and compositions taught by the reference are encompassed by the instant claims.

In view of the foregoing amendments to Claims 1-4, 7-8, 22 and 23, Applicants traverse this rejection for the following reasons.

Claim 1 of the instant application (upon which Claims 2-4 and 7-8 ultimately depend) is directed to compounds of the following formula (I):



where  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^{4a}$ ,  $R^{4b}$ ,  $R^5$  and  $R^6$  are as defined in the above claims. Claims 22 and 23 are directed to pharmaceutical compositions comprising the compounds of formula (I). Of particular interest with respect to the cited references are the choices for  $R^{4a}$  and  $R^{4b}$  in the compounds of formula (I).

Applicants respectfully submit that all of the compounds disclosed in either Oshida or Lettre *et al.* have one of the substituents corresponding to the  $R^{4a}$  and  $R^{4b}$  substituent in the compounds of Formula (I) above as hydrogen and the other substituent corresponding to the  $R^{4a}$  and  $R^{4b}$  substituent is an alkyl group. In particular, Lettre *et al.* and Oshida both disclose compounds wherein the substituent corresponding to either the  $R^{4a}$  or  $R^{4b}$  group in the compounds of formula (I) is hydrogen and the other substituent corresponding to either the  $R^{4a}$  or  $R^{4b}$  group in the compounds of formula (I) is 6-methylheptan-2-yl.

Applicants have amended Claims 1-4, 7, 22 and 23 to remove "alkyl" as a choice for the  $R^{4a}$  or  $R^{4b}$  substituent in the compounds of formula (I). In addition, Claim 8 is amended to remove the sole compound disclosed in the specification wherein  $R^{4a}$  and  $R^{4b}$  are both alkyl (*i.e.*, wherein both are methyl). Thus, the claims, as amended, do not encompass compounds of formula (I) wherein one of  $R^{4a}$  and  $R^{4b}$  is an alkyl group, nor do they encompass compounds of formula (I) wherein  $R^{4a}$  and  $R^{4b}$  are both an alkyl group. Consequently, compounds such as

those disclosed in Oshida and Lettre *et al.*, which require that one of the substituents corresponding to the R<sup>4a</sup> and R<sup>4b</sup> substituent in the compounds of formula (I) is an alkyl group, are not anticipatory of the compounds in the aforementioned amended claims.

In view of this amendment to the claims, Applicants respectfully submit that the compounds disclosed in Lettre *et al.* and Oshida do not anticipate the currently claimed compounds or pharmaceutical compositions. Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 7, 22 and 23 under 35 U.S.C. 102(b) in view of Lettre *et al.* and in view of Oshida be withdrawn and that these claims be allowed to issue forthwith.

#### Objection to Claim 8

The Examiner objected to Claim 8 because it is dependent upon a rejected base claim. Applicants respectfully submit that the aforementioned amendment to Claim 7 should place Claim 8 in a position for allowance by overcoming the rejection of the base claim (*i.e.*, Claim 7) in view of the cited art.

#### Request for Rejoinder of Claims 24-26

Applicants have amended withdrawn Claim 24 to remove the phrase "in isolation or in a mixture" to further the allowance of this application. In addition, Applicants have amended withdrawn Claims 24 and 25 to remove "alkyl" as a choice for the R<sup>4a</sup> or R<sup>4b</sup> substituent in the compounds of formula (I) used in the method claimed therein. Accordingly, Applicants respectfully submit that process Claims 24 and 25 now include the limitations of product Claims 1 and 22, and therefore respectfully request rejoinder of withdrawn Claims 24, 25 and 26 (which is dependent upon Claims 24 and 25) in accordance with M.P.E.P. § 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995).

Applicants respectfully submit that all of the claims remaining in the application are now clearly allowable. Favorable consideration and an early Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,  
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